

REMARKS

Election in Response to Restriction Requirement

The Examiner has made a restriction requirement between the following two Groups:

Group I, claim(s) 1-9, drawn to a *pharmaceutical composition* for the treatment or prophylaxis of cancer.

Group II, claim(s) 9-10, drawn to a *method of treatment or prophylaxis* of cancer with said pharmaceutical composition.

The Examiner notes that claim 9 is a non-statutory "use" claim which may be considered either a product or a method (the pharmaceutical composition or method of treatment, respectively). Applicant is requested to choose whether claim 9 will be considered with Group I or Group II and to amend the claim accordingly. This issue has been obviated by the cancellation of all non-elected claims 1-9 and elected claims 9-10, and their replacement with new method claims 11, 12 and 13, which are in a proper method of treatment form.

The Examiner has also required Applicant to elect a single species of the Src inhibitors listed in claims 2-6, to which the claims shall be restricted if no generic claim is finally held to be allowable, and to also identify the claims readable on the elected species, including any claims subsequently added. In response to this requirement for an election of species, Applicant provisionally elects the species of the Src inhibitor of claim 6, 4-(2-chloro-5-methoxyanilino)-6-methoxy-7-(N-methylpiperidin-4-ylmethoxy)quinazoline. New claims 11 and 12 are readable on the elected species.

It is understood that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Claim Amendments

Claims 1-9 (composition) have been cancelled as being non-elected.

Elected claims 9 and 10 (method) have been cancelled and replaced with new method claims 11-13, which, in an effort to simplify the issues and expedite the allowance of this application, are more specifically directed toward a method for the treatment or prophylaxis of

pancreatic cancer comprising the administration of one of two specifically named Src inhibitors in combination with gemcitabine. Support for this method of treatment or prophylaxis of cancer is generically found in original claim 10 and its dependence on original claim 1, and support for the usefulness of combinations in accordance with the invention in the synergistic treatment or prophylaxis of pancreatic cancer is found, *inter alia*, on page 21, lines 21-23. Thus:

- New claim 11 is specifically limited to the treatment or prophylaxis of pancreatic cancer by administration of synergistically effective therapeutic amounts of a Src inhibitor selected from 4-(2-chloro-5-methoxyanilino)-6-methoxy-7-(N-methylpiperidin-4-ylmethoxy)quinazoline and 4-(6-chloro-2,3-methylenedioxyanilino)-7-(2-piperidinoethoxy)-5-tetrahydropyran-4-yloxyquinazoline and pharmaceutically-acceptable acid-addition salts thereof; and gemcitabine.
 - Support for the Src inhibitor 4-(2-chloro-5-methoxyanilino)-6-methoxy-7-(N-methylpiperidin-4-ylmethoxy)quinazoline and pharmaceutically-acceptable acid-addition salts thereof (hereinafter described as “compound 1”; also denoted as “Src-1”) is found in original claim 6 and in the specification description on page 19, line 30 to page 20, line 1; and support for the administration of synergistically effective therapeutic amounts of compound 1 and gemcitabine for the treatment or prophylaxis of pancreatic cancer is found at page 22, lines 13-17, and also in the test or demonstration of the activity of this combination at page 28, line 3 through page 29, line 9.
 - Support for the Src inhibitor 4-(6-chloro-2,3-methylenedioxyanilino)-7-(2-piperidinoethoxy)-5-tetrahydropyran-4-yloxyquinazoline and pharmaceutically-acceptable acid-addition salts thereof (hereinafter described as “compound 2”; also denoted as “AZD0530”) is found in original claim 3 and in the specification description at page 19, lines 16 to 20; and support for the administration of synergistically effective therapeutic amounts of compound 2 and gemcitabine for the treatment or prophylaxis of pancreatic cancer is found at page 21, line 29 to page 22, line 2.
- New claim 12 is specifically directed toward the treatment or prophylaxis of pancreatic cancer by administration of synergistically effective therapeutic amounts of the Src inhibitor

4-(2-chloro-5-methoxyanilino)-6-methoxy-7-(N-methylpiperidin-4-ylmethoxy)quinazoline and pharmaceutically-acceptable acid-addition salts thereof (compound 1) and gemcitabine, with original specification and claim support therefore being as indicated above with respect to new claim 11.

- New claim 13 is specifically limited to the treatment or prophylaxis of pancreatic cancer by administration of synergistically effective therapeutic amounts of the Src inhibitor 4-(6-chloro-2,3-methylenedioxyanilino)-7-(2-piperidinoethoxy)-5-tetrahydropyran-4-yloxyquinazoline and pharmaceutically-acceptable acid-addition salts thereof (compound 2) and gemcitabine, with original specification and claim support therefore being as indicated above with respect to new claim 11.

These amendments to the claims are being made without waiver or prejudice to Applicant's rights to pursue any deleted subject matter in one or more continuing application.

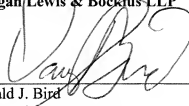
It should be clear from the above that no new matter has been introduced by the above amendments, and entry thereof is respectfully requested. Following entry of these amendments, claims 11-13 remain pending in this application.

Information Disclosure Statement

The Examiner's attention is called to the Supplemental Information Disclosure Statement filed herewith, which includes a table of technically related US applications of Applicant's assignee and the current status thereof. It is understood that the Examiner has ready access to electronic copies of these applications, but please advise the undersigned if anything further is required.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,
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